

8EHQ-0394-12952



2030 DOW CENTER
March 18 1994

The Dow Chemical Company
Midland, Michigan 48674



8EHQ-94-12952
INIT 03/23/94



88940000194

CERTIFIED MAIL--RETURN RECEIPT
REQUESTED

OFFICE OF POLLUTION
PREVENTION AND TOXICS

91 MAR 23 AM 7:43

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Attn: 8(e) Coordinator

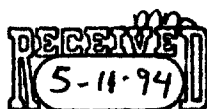
Re: Aluminum Nitride (CAS Number 24304-00-5)

Dear Sir/Madam:

The following information is being submitted by The Dow Chemical Company (Dow) pursuant to current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substance Control Act. Dow has made no determination as to whether a significant risk of injury to health or the environment is actually presented by the findings.

As part of an inhalation toxicity study of aluminum nitride (AlN), five Fischer 344 rats of both sexes were exposed for four weeks to aerosols of AlN at each of the following concentrations: 0, 2, 10, or 70 mg/m³. At the end of four weeks of exposure there was a mild inflammatory response in the lungs of rats at the 70 mg/m³ exposure. In the 2 and 10 mg/m³ groups there was little or no evidence of a tissue reaction in the lungs, other than phagocytosis of these material. At the lower doses, virtually all of the visible test material was within alveolar macrophages. At the 70 mg dose, approximately 25% of the test material was "free," in that either unphagocytized or freed from dead macrophages.

Following the 4-week exposure, separate groups of rats were held for a 10-week post-exposure period. Preliminary histopathologic examination of the lungs indicated that at 2 mg/m³ the test material was present within alveolar macrophages and there were widely scattered small areas of mild inflammation characterized by slight alveolar type II cell proliferation and occasional neutrophils. At 10 mg/m³, the changes described above were more apparent, and there were reactive changes in bronchial



2 pgs.

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March 18, 1994
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associated lymphoid tissue (BALT). At 70 mg/m³, much of the test material was trapped within proteinaceous material filling many of the alveolar spaces. Alveolar type II cell proliferation and the BALT reaction were noted. Neutrophils were more common than at lower exposure levels and some contained phagocytized test material. Overall, the reaction was characterized as a proliferative pneumonitis.

These preliminary data indicate a dose related response in the lungs of rats at the three exposure levels studied. A written report is not yet available.

Sincerely,



Paul A. Wright
Senior Attorney
Legal Department
517/636-1853



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Paul A. Wright
Senior Attorney, Legal Department
The Dow Chemical Company
2030 Dow Center
Midland, Michigan 48674

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 27 1994

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned §8(e) number when submitting follow-up or supplemental information, and refer to the reverse side of this page for TSCA Information Requester.

All TSCA §8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA §8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12952 A



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contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage:

DEC 14 1994

NON-CAP

CAP

Submission number:

12952A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.):

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document:

0

1

2

pages

1, 2

pages

1, 2

Notes:

Contractor reviewer:

FOR

Date:

11/1/94

SEQ. A

TYPE: INT. SUPP FL WP

SUBMITTER NAME: Dow Chemical Company

SUB. DATE: 03/18/94 OTS DATE: 03/23/94
CHEMICAL NAME:

CSRAD DATE: 05/11/94

CASE
24304-00-5

INFORMATION TYPE:

REC

INFORMATION TYPE:

0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL. TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

33

INFORMATION TYPE:

P F C	
0241	IMMUNO (ANIMAL)
0242	IMMUNO (HUMAN)
0243	CHEM/PHYS PROP
0244	CLASTO (IN VITRO)
0245	CLASTO (ANIMAL)
0246	CLASTO (HUMAN)
0247	DNA DAMAGE/FAIR
0248	PRODUCE/PROC
0251	MSDS
0259	OTHER

TRACE DATA **NON-CBI INVENTORY**

ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

10

Norm-Gap

SPECIES

RAT

TOXICOLOGICAL CONCERN:

Low

MED

1000000

PRODUCTION:

USP

~~VOLUNTARY ACTIONS~~

0401 NO ACTION PURITY

STUDIES PLANNED FOR 1971

THE UNIVERSITY OF CHICAGO PRESS

PROFESSIONAL LIABILITY INSURANCE

APPLAUSE DISCONTINUED

4007 PRODUCTION DISCONTINUED

CONFIDENTIAL

0 0 0 >

<ID NUMBER>

8(e)-12952A >

<TOX CONCERN>

M >

<COMMENT>

SUBACUTE INHALATION TOXICITY IN RATS IS OF MODERATE CONCERN, BASED ON PRELIMINARY RESULTS. DOSAGE (4 WEEKS) FOR GROUPS OF 5 MALES AND 5 FEMALES ARE AS FOLLOWS: 2 MG/M3, 10 MG/M3, OR 70 MG/M3. NO MORTALITY WAS REPORTED. THE PATHOLOGICAL SIGN REPORTED WAS A MILD INFLAMMATORY RESPONSE IN THE LUNGS AT THE HIGHEST DOSE, WITH PHAGOCYTOSIS OF THE TEST MATERIAL IN THE LUNGS OF ALL TREATED ANIMALS. HISTOPATHOLOGICAL FINDINGS IN THE LUNGS WERE ALVEOLAR CELL PROLIFERATION, NEUTROPHILS, REACTIVE CHANGES IN BRONCHIAL ASSOCIATED LYMPHOID TISSUE, AND PROLIFERATIVE PNEUMONITIS. \$\$\$\$

-CPSS- 0406951403